REMARKS

Claims 49, 54, 56-58, 63, 66, 72, 75, 77, 79, and 80 are pending. Claims 1-48, 50-53, 55, 59-62, 64, 65, 67-71, 73, 74, 76 and 78 have been canceled. The pending claims have been amended to clarify the subject matter Applicants regard as the invention. These amendments do not add new matter, are fully supported by the specification, as well as the claims as originally filed. Reconsideration of the pending claims in view of the amendments and remarks provided herein is respectfully requested.

Claim 55 is definite

Claim 55 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to further limit claim 54, the claim from with the rejected claim depends. Claim 55 had been cancelled.

The Pending Claims are Adequately Supported by an Enabling Disclosure

Claims 49, 54-63, 66, 72, 75, 77, 79, and 80 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner has raised a number of issues under this rejection and each is discussed below.

As a preliminary matter, "[t]o be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' ... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)).

In the first grounds of rejection, the Examiner alleged that the specification fails to provide a nexus between the expression of the 254P1D6B variants in any cancer, not merely those that

express the 254P1D6B protein. Applicants disagree. Nevertheless, solely to clarify the subject matter which is regarded as the invention, Applicants have amended claim 75 to specify that the cancerous tissues being examined are those that express the 254P1D6B protein.

The specification as filed contains Northern blot and PCR data which shows that the gene of interest is upregulated in a variety of cancers. (See Figures 14 to 16.) This data shows a sufficient nexus between the upregulation of expression of the so-called generic 254P1D6B protein (SEQ ID NO:3) to allow one of ordinary skill in the to reasonably assume that reagents used which detect variants of the 254P1D6B protein will also serve as markers for cancer in test tissues. Additionally, data shown in Figure 13 indicates the likelihood of at least one transmembrane domain for the protein. This data taken as a whole shows that one of ordinary skill in the art would reasonably conclude that the protein of interest is expressed in tumor cells and would be detectable using an antibody exposed to such a cell.

The Examiner further alleged that one of ordinary skill in the art would be "forced" to determine if expression patterns for the variants matched those of the generic 254P1D6B protein (SEQ ID NO:3). Applicants disagree. Genetic variation between the claimed variants does not necessarily imply that each variant has a unique function. Moreover, the biological function of the protein is irrelevant to how the claimed subject matter is used. Specifically, the claimed proteins as a group are used as a family of markers to detect cancer in a test tissue sample by monitoring expression levels.

The Examiner next rejected claims 58-62, 79 and 80 as allegedly lacking enabling support. First, it was alleged that a target for any antibody based therapy, specifically those which seek to evoke complement and ADCC-mediated cell killing require a cell surface target and cites to Abbas, et al. for support. However, this argument mischaracterizes the reference. Abbas, et al. do not say that the antibody must bind a cell surface target to be effective. Instead the reference simply says that, "Thus, ADCC is most efficient when the target cell is precoated with antibody. " Id. at 58, 1st col. In other words, the target cell needs to be associated with the antibody to produce efficient ADCC, it does not say that this associate be produced by the targeting of a cell surface protein. Nevertheless, as discussed above, there is evidence in the specification that the 254P1D6B protein is

present on the cell surface. This argument and evidence notwithstanding, the pending claims relating to T-cell immune responses have been deleted. Applicants reserve the right to pursue this subject matter in a related case.

Claim 54

The Examiner alleged that one of ordinary skill in the art would have to engage in undue experimentation to determine which peptides encompassed by claim 54 would have activity. To support an enablement rejection, the Examiner must show that the amount and nature of the required experimentation is "undue." Enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive." *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). "'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)).

Here, the type of experimentation necessary to identity immunogenic peptides is merely routine, particularly in view of the extensive teachings provided both in the art as a whole as well as in the specification as filed. As such, Applicants submit that the Examiner has failed to make out a *prima facie* case of lack of enablement for claim 54. Therefore, the present rejection should be withdrawn.

Polynucleotide Claims

Claims 63, 66, and 72 were rejected for allegedly lacking enablement because there was allegedly no evidence provided which demonstrated a nexus between a cancer state and the claimed sequences. For the reasons discussed above, Applicants disagree. The specification provides actual data using sequences falling within the scope of the rejected claims to detect the expression of the gene of interest in cancer samples as opposed to normal samples. This data clearly demonstrates how one of ordinary skill in the art could use the claimed nucleotides to detect cancer. In view of

this data, the Examiner is requested to withdraw the enablement rejection as it relates to claims 63, 66, and 72.

Claims 54-56 Satisfy the Written Description Requirement

Claims 54-56 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). An applicant need not describe exactly the subject matter claimed in the specification in order to satisfy the written description requirement. *See Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000).

> "What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient")." M.P.E.P. § 2163.

Applicants have described the sequences which would be used to produce the peptides, how to use the peptides to raise an immune response, and how to test for such a response. What has not been literally described was conventionally known in the art at the time the present application was filed. In view of this, Applicants submit that one of ordinary skill in the art could readily conclude that Applicants' were in possession of the invention at the time the application was filed. Accordingly, this rejection is traversed and should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **511582008100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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